

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION**

DOUGLAS KAYE

Plaintiff

VS.

SYNTHES (U.S.A.)

Defendant

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CAUSE NO. 4:05-CV-02809

AFFIDAVIT OF JACK E. LEMONS, PH.D.

STATE OF ALABAMA §
 §
COUNTY OF JEFFERSON §

BEFORE ME, the undersigned authority on this date personally appeared, Jack E. Lemons, Ph.D., known to me to be the person whose name is subscribed to the following instrument, and having been by me duly sworn, upon his oath deposes and states as follows:

1. “My name is Jack E. Lemons, Ph.D. I am over 18 years of age, and am otherwise competent to make this Affidavit. I have personal knowledge of the facts stated herein and they are true and correct.
2. “I am currently a Professor and the Director of Laboratory and Surgical Research at the University of Alabama at Birmingham. I have 36 years of experience as an educator of medical residents, faculty and staff within the specialty of orthopedic biomaterials and biomechanics. Additionally, I spent 3 years as a National Institute of Health fellow studying medicine and dentistry. Subsequently, I have provided the basic and applied science lectures for the education and training of orthopedic surgeons, other specialty residents and graduate students. One aspect of this activity has been a focus on fracture fixation devices, in part because our university is a Level One trauma center. I have presented hundreds of lectures and peer reviewed publications within the discipline and over the years. I have directed

a laboratory research program with a central focus on surgical implant device retrieval and analysis. This program is now funded, in part, through a grant from the National Institute of Biomedical Imaging and Bioengineering. Additionally, I previously chaired the American Society for Testing and Materials (ASTM) Committee FO4 on Medical Devices and currently chair the USA TAG of the International Standards Organization Committee (ISO) TC150 on medical devices. Overall, my background has emphasized education, research and clinical service, and I have extensive experience in the design, manufacture and uses of internal fracture fixation devices. A copy of my Curriculum Vitae is attached hereto as Exhibit A.

3. “Prior to forming my opinions in this case I reviewed medical records and documentation related to the treatment of Mr. Kaye, including the hospital and clinic records from Sweetwater Radiology Associates, Southwest Bone and Joint Clinic, Fletcher Allen Health Care, Sugar Land Surgical Hospital and Houston Orthopedic Medicine. I also reviewed documentation on the Synthes plate system, including catalog pages, Synthes’ package inserts, plus a copy of the deposition of Dr. Timothy Sitter. Following this review, I authored a report dated July 25, 2006, reflecting my opinions in this matter. A true and correct copy of my report is attached hereto as Exhibit B.
4. “Metallic plates, such as the subject plate, are implanted to provide rigid fixation of bone fractures immediately after a fracture event or subsequently after a period of conservative non-surgical treatment, as was the situation for Mr. Kaye. The specifics of treatment, such as the plate and surgical placement, are based on clinical research and experience where the orthopedic surgeon decides what is best for each particular patient and condition. Importantly, the details of the patient’s anatomy, clinical history, lifestyle, functional activities and healing capacity are unique to the individual. Therefore, the treatment selection must be based on the *in vivo* circumstances and no single fixation system is capable of providing optimal conditions for all clinical circumstances. Considering the events of this particular plate’s biomechanical fracture, long term experience in the scientific and clinical literature has shown that metallurgical bone plates break, in general, because of multiple loading cycles, a single overload event that exceeds the fracture strength of the plate system, or a combination of lower magnitude load cycling and a final overloading event. These basic principles are taught to orthopedic surgeons as a part of their academic education.

5. “Considering the implantation time (of the subject plate only) of about 5 weeks for Mr. Kaye, several key items are important to this plate fracture. The observed status of minimal bone healing during the 5-week period would have resulted in increased and localized load distribution to the subject plate system. The repetitive loading associated with employment and scissor sharpening that requires arm and hand position and holding, plus yard work and other household activities, would have caused high numbers of loading cycles to the bone and plate region. The event of moving a refrigerator would have caused a high magnitude load to the clavicle bone and plate region and, thereby, final fracture of the plate. Therefore, in my opinion, this plate fractured due to a combination of many loading cycles leading to localized stress and strain hardening within the plate followed by a high load that induced local stresses within the plate that exceeded the strength of the plate. The location of the fracture at a screw hole resulted from the reduced dimension of the one-third tubular Synthes 6-hole plate with collar at the screw hole location. The localized internal stresses at the hole region would be in proportion to the reduced planar cross sectional area at that site. In general, laboratory and clinical retrieval studies have shown plate fractures at screw hole locations, as observed in this case.
6. “Given the circumstances associated with the clinical status of Mr. Kaye, the one-third tubular Synthes 6-hole plate with collar made from 316L stainless steel was an appropriate choice from a biomaterial viewpoint. Again, this plate, as with other devices of this type, is intended as an aid to fracture healing, and if the bone site does not heal, plate breakage is anticipated after some period of biomechanical loading. Such an anticipated event is part of the education program for orthopedic surgeons, such that it is well recognized in the community of orthopedic surgeons trained in the properties and uses of bone fixation plates that these plates can and do occasionally break without being in any way defective.
7. “My experiences within the discipline and especially within national and international standards organizations have demonstrated that orthopedic manufactures’ comply with national (ASTM) and international (ISO) requirements for design, metallurgy and manufacturing practices. This includes multilevel quality analysis and quality control programs that are independently evaluated and validated by regulatory agencies such as the Food and Drug Administration. In my professional opinion, this plate fractured due to biomechanical overloading that imposed mechanical tension and shear conditions from *in vivo* bending and torquing that was caused

by a combination of repetitive loading, the activity of moving a heavy object, and the incomplete healing of the bone at 5 weeks post implantation. In all probability, this plate system was not defective due to design, metallurgy or manufacturing.

"Further affiant sayeth not."

Signed this 23 day of October, 2006.

Jack E. Lemons, PhD
Jack E. Lemons, Ph.D.

SUBSCRIBED AND SWORN TO BEFORE ME on this the 23 day of October, 2006,

to certify which witness my hand and seal of office.

Wesley W. Ray
Notary Public in and for the State of Alabama
My Commission Expires: _____

**NOTARY PUBLIC STATE OF ALABAMA AT LARGE
MY COMMISSION EXPIRES: Aug 10, 2007
BONDED THRU NOTARY PUBLIC UNDERWRITERS**

JACK E. LEMONS
CURRICULUM VITAE

PERSONAL HISTORY

Born: Birth Date: January 20, 1937
Birth Place: St. Petersburg, Florida
Citizenship: United States

Family: Married: Benta Lemons
Children: Paul and Hans

Office Address: University of Alabama at Birmingham
1919 Seventh Avenue South, 616 SDB, Box 61
Birmingham, Alabama 35294-0007
(205) 934-9206 • Fax: (205) 975-6108
E-Mail: Jack.Lemons@ortho.uab.edu

Home Address: 229 Richmar Drive
Birmingham, Alabama 35213
(205) 879-0909

EDUCATION

1960 A.A. - St. Petersburg Jr. College (Engineering Associate)

1963 B.S. - University of Florida (Metallurgy and Materials Engineering)

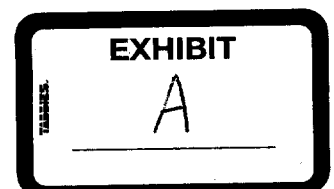
1964 M.S. - University of Florida (Metallurgy, Solid State Physics)

1968 Ph.D. - University of Florida (Metallurgy, Solid State, Physics, Inorganic Chemistry)

1971-73 University of Alabama at Birmingham (NIH-sponsored Fellowship in Medicine and Dentistry)

ACADEMIC EXPERIENCE

Present: Professor, Department of Prosthodontics and Biomaterials
University of Alabama School of Dentistry
Professor, Department of Surgery
University of Alabama School of Medicine
Director - Division of Orthopaedic Laboratory Research
Professor of Biomedical and Materials Engineering
University of Alabama at Birmingham, Birmingham, AL



Academic Experience (Continued)

- Professor, Joint Materials Science Program
University of Alabama, Tuscaloosa, AL
University of Alabama in Huntsville, Huntsville, AL and
University of Alabama at Birmingham, Birmingham, AL
Interim Director, Biomedical Implant Center, Sr. Scientist, Metabolic Bone
Disease, Cell Adhesion, Matrix and Minority Health Research Centers
University of Alabama at Birmingham, Birmingham, AL
Adjunct Professor of Prosthodontics
University of Pittsburgh School of Dental Medicine
- 1978-1990: Professor and Chairman, Department of Biomaterials
University of Alabama School of Dentistry
Professor of Biomedical and Materials Engineering
Associate Professor of Surgery and Public Health
Director - Division of Orthopaedic Laboratory Research
University of Alabama at Birmingham, Birmingham, AL
- 1973-1977: Associate Professor of Dentistry, Engineering and
Engineering Biophysics
Assistant Professor of Surgery
University of Alabama at Birmingham, Birmingham, AL
- 1971-1973: Instructor and Student in Medical Program,
Department of Engineering Biophysics
University of Alabama at Birmingham, Birmingham, AL
- 1970-1971: Assistant Professor of Materials and Bioengineering,
Division of Interdisciplinary Studies
Clemson University, Clemson, SC
- 1968-1970: Assistant Professor of Engineering (evenings)
College of Engineering
University of Alabama at Birmingham, Birmingham, AL
- 1963-1968: Graduate Research Assistant
Department of Metallurgy and Materials Engineering
University of Florida, Gainesville, FL
- 1962-1963: Research Associate
Department of Metallurgy and Materials Engineering
University of Florida, Gainesville, FL

INDUSTRIAL EXPERIENCE

1968-1970: Head, Physical Metallurgy Section and Research Metallurgist
Southern Research Institute, Birmingham, AL

1957-1959: Surveyor, Heavy Equipment Operator,
Cone Brothers Construction Company, Tampa, FL

1954-1957: Owner and Operator,
J.E. Lemons' General Repair and Machine Shop
St. Petersburg, FL

SOCIETY MEMBERSHIPS

Alpha Sigma Mu (Honors Engineering Society)
American Academy of Implant Dentistry and International Congress (Honorary Member)
American Academy of Orthopaedic Surgery
American Association for the Advancement of Science
American Board of Forensic Examiners
American Institute for Metallurgical, Mining, and Petroleum Engineers
American Society for Metals (Fellow)
American Society for Testing and Materials (Fellow)
American Society of Osseointegration (Diplomate)
International Association for Dental Research
Omicron Kappa Upsilon (Honors Dental Society)
Orthopaedic Research Society
Sigma Xi (Research Society)
Society for Biomaterials (Fellow, Biomaterials Science and Engineering)
Southern Medical Association
Alabama Orthopaedic Society

EDITORIAL AND JOURNALS

American Dental Association Council on Scientific Affairs - Consultant
Bio-Medical Materials and Engineering
Clinical Oral Implants Research
Dental Implant Briefings
Dental Implant Perspectives
Dental Implantology Update
Journal of Biomedical Materials Research (Editorial Board)
Journal of Dental Research
Journal of Oral Implantology - Associate Editor
Journal of Clinical Implantology (Section Editor)

SERVICE ACTIVITIES

International Exchange Programs in Dental and Surgical Implant Materials Research: Nordic Institute for Odontological Materials Research, Central Institute for Industrial Research, and University of Oslo, Oslo, Norway. Dental University, Guatemala City, Guatemala, and three Universities in Brazil.

Continuing Education Lectures

Consultation on Surgical Implant and Dental Biomaterials and Biomechanics

PATENTS

U.S. Patent Number 5, 273, 964 entitled "Inorganic And Organic Composition for Treatment of Bone Lesions

PUBLICATIONS

1. Lemons, J.E.: Grain Boundary Hardness in Alpha Brass. Proceedings from the Conference on Metallurgical Research at the University of Florida, Cape Canaveral, FL, 1966.
2. Lemons, J.E.: Grain and Twin Boundary Effects on Hardness in Alpha Brass. Symposium Proceedings: The Many Facets of Grain Boundaries, University of Florida, Gainesville, FL, 1967.
3. Rhines, F.M. and Lemons, J.E.: Critique on Grain Size Measurement. Keynote Paper: Society of AIME, 1967.
4. Lemons, J.E. and Rhode, F.C.: Implementation of a Model 1000 Magneform Machine for Impact Hardness Testing. Final Report: Contract No. NASA 2971A10, 1968.
5. Lemons, J.E. and Picklesimer, M.L.: Superplasticity in Steel. Final Report: Project 1851, Southern Research Institute, Birmingham, AL, 1968.
6. Lemons, J.E.: Hardness: Its Meaning and Measurement. Southern Research Institute, Birmingham, AL, 1969.
7. Lemons, J.E. and Picklesimer, M.L.: Superplasticity in Steel. Final Report: Project 2219, Southern Research Institute, Birmingham, AL, 1970.

8. Hulbert, S.F., Klawitter, J.J., Lemons, J.E., and Wilson, C.N.: Fabrication and Evaluation of Ceramic Implant Materials for Replacement of Teeth and Bone: Mechanical Strength Testing of Highly Porous Calcium Aluminate Ceramics. Final Report: Contract No. NIH-70-2122, 1971.
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10. Lemons, J.E.: A Study of Grain Morphology in Ultrafine Grain Size Metals and Alloys. Final Technical Report: AMMRC CTR-72-13, 1972.
11. Lemons, J.E. and Niemann, K.M.W.: Investigations on the Relationship Between Applied Electrical Potential, Structure and Strength for Rabbit Tibia. Symposium Proceedings of Prostheses and Tissue, The Interface Problem, Clemson University, Clemson, SC, 1973.
12. Lemons, J.E.: Final Report: Preliminary Mechanical Property Study of Vitreous Endosteal Implants. Vitreous Corporation, University of Alabama at Birmingham, 1974.
13. Lemons, J.E. and Richardson, W.C.: Quantitative Stereological Investigations of Porous Alumina Implant Biomaterials. Journal of Dental Research 55, DMG Microfilms, 1974.
14. Lemons, J.E.: Biomaterials Science Studies of Porous Implant Materials. Invited Paper: Biomedical Surfaces and Membranes, Conference sponsored and published by 3M Company, St. Paul, MN, July, 1974.
15. Lemons, J.E. and Olafsson, S.: Biomaterials Science Methodology for the Investigation of Tissue-Porous Biomaterials Interfaces. Microstructural Science III, 931-939, 1975.
16. Lemons, J.E.: Biomaterials Science Protocols for Clinical Investigations on Porous Alumina Ceramic and Vitreous Carbon Implants. Journal of Biomedical Materials Research 6, 9-16, 1975.
17. Lemons, J.E.: Investigations on the Response of Primate and Rabbit Marrow, Bone and Tissues to Porous Titanium Implants. Journal of Dental Research 54B, 166-170, 1975.
18. Lemons, J.E.: Biomaterial Considerations for Dental Implants, Part I: Metals and Alloys. Alabama Academy of General Dentistry Sponsored Symposium on Dental Implants, Oral Implantology 4, 503-515, 1975.
19. Lemons, J.E.: Investigation of a Composite Tendon Design. First Annual Report, Orthopaedic Research and Education Foundation, University of Alabama at Birmingham, 1975.

20. Lemons, J.E.: Response of Combined Electrical Stimulation and Biodegradable Ceramics. Annual Report: Contract DAMD17-75-C-5044, U.S. Army Research and Development Command, Report No. 1, 1-35, 1975.
21. Lemons, J.E. and Richardson, W.C.: Quantitative Stereology Investigations of Porous Alumina Implant Biomaterials. Journal of Dental Research 55, 111-114, 1976.
22. Lemons, J.E.: Qualitative and Quantitative Optical Microscopy Investigations of Inorganic Surgical Implant Material to Tissue Interfaces. Microstructural Science IV, 131-135, Elsevier, NY, 1976.
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26. Lemons, J.E.: Response of Combined Electrical Stimulation and Biodegradable Ceramics. Annual Report: Contract DAMD17-75-C-5044, U.S. Army Research and Development Command, Report No. 2, 1-44, 1976.
27. Lemons, J.E. and Alling, C.C.: Considerations on Prestretching Metallic Wires. Journal of Oral Surgery 35, 237, 1977.
28. Lemons, J.E.: Experimental Approaches to Tooth and Bone Replacement-Extractions, Implants and Transplants. J. Navia, Ed., Animal Models in Dental Research, 363-389, University of Alabama Press, University, AL, 1977.
29. Lemons, J.E.: Surface Conditions for Surgical Implants and Biocompatibility. Journal of Oral Implantology 7, 362-374, 1977.
30. Lemons, J.E.: Long Term Tissue Response to Porous Biodegradable Ceramics in Skeletal Defects. Annual Report: Contract DAMD17-75-C-5044, U.S. Army Research and Development Command, Report No. 3, 1-30, 1978.
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33. Lemons, J.E.: Response of Combined Electrical Stimulation and Biodegradable Ceramics. Annual Report: Contract DAMD17-75--C-5044, U.S. Army Research and Development Command, Report No. 4, 1-30, 1979.
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35. O'Neal, S.J., Powell, W.D., and Lemons, J.E.: Quantitative and Qualitative Color Evaluations for Porcelain to Alloy Prostheses. Journal of Dental Research 59, DMG Microfilm No. 659, 1980.
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45. Lemons, J.E.: Response of Combined Electrical Stimulation and Applied Laboratory and Clinical Studies on Biodegradable Ceramics. Annual Report: Contracts DAMD17-75-C-5044 and DAMD17-79-C-9173, U.S. Army Research and Development Command, Report No. 5, 1-20, 1981.
46. Lemons, J.E.: Edentulous Ridge Augmentation. D.C. Smith and D.F. Williams, Eds., Biocompatibility of Dental Materials, 4, 231-247, CRC Press, Boca Raton, FL, 1982.
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55. Lemons, J.E.: Aluminum Oxide Ceramics as Biomaterials. P.Vicenzini, Ed., Ceramics in Surgery, 117-126, Elsevier, Amsterdam, 1983.
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58. Chang, C.S., Matukas, V.J., and Lemons, J.E.: Histologic Study of Hydroxyapatite as an Implant Material for Mandibular Augmentation. Journal of Oral and Maxillofacial Surgery 41, 729-737, 1983.
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64. Turner, G.E., Fischer, T.E., Castleberry, D.J. and Lemons, J.E.: Intrinsic Color of Isophorone Polyurethane for Maxillofacial Prosthetics. Part II: Color Stability. Journal of Prosthetic Dentistry 51, 673-675, 1984.
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67. Ward, J.J., Nasca, R.J., Lemons, J.E., and Bidez, M.W.: Cyclic Testing of Harrington and Luque Spinal Instruments. Proceedings of the Third Southern Biomedical Engineering Conference, 1984.
68. Bidez, M.W., Lemons, J.E., and Isenberg, B.P.: Displacement Profiles of gold and Nickel-Based Dental Bridge Systems Under Low loading Conditions. Proceedings of the Third Southern Biomedical Engineering Conference, 1984.
69. Lemons, J.E. and Lucas L.C.: Materials, Substrate Properties and Corrosion of Porous Materials. Proceedings of the Harrington Research Center Symposium on Uncemented Total Joint Replacements, 1-9, University Park Press, Phoenix, AZ 1985.